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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/613,201	07/03/2003	Hector F. DeLuca	1256-00915	4564

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EXAMINER	
BADIO, BARBARA P	

ART UNIT	PAPER NUMBER
1616	

DATE MAILED: 06/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/613,201	DELUCA ET AL.	
	Examiner	Art Unit	
	Barbara P. Badio, Ph.D.	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-31* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

First Office Action on the Merits

Double Patenting

1. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

2. Claims 1-31 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-31 of copending Application No. 10/657,533. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

3. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claims 3-5 and 18-30 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 16-24, 30-37, 56-58, 61, 62 and 68 of copending Application No. 10/235,244. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are both drawn to methods of treating psoriasis or cancer by administering a vitamin D derivative. The difference between the two applications is based on the scope of the claimed compounds. Unlike, the copending Application No. 10/235,244, the present application is limited to 2-methylene-19-nor-20(S)-25-methyl-1α-hydroxy-vitamin D compounds. However, the copending Application No. 10/235,244 encompasses vitamin D compounds as defined by claim 24 wherein R^6 and R^7 each represent hydrogen, R^8 represents hydroxy or a protected hydroxy, R^9 and R^{10} together represent the group $=R^{11}R^{12}$ wherein R^{11} and R^{12} each represent hydrogen, Z is Y wherein m is 0, R_1 is hydrogen, n is 3 and each of R_2, R_3, R_4 and R_5 each represent a C_1 alkyl (CH_3). The motivation to make said compounds would be based on the disclosure of copending Application No. 10/235,244 of the use of said compounds in treating various disorders as recited by the instant claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

5. Claims 1-20 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 14, 17-27, 30 and 33 of U.S. Patent No. 5,843,928. Although the conflicting claims are not identical, they are not patentably distinct from each other because they both recite compounds wherein each of R_6 and R_8 represent hydrogen, Z is Y wherein m is 0, R_1/R_2 is hydrogen/methyl, n is 3 and R_3, R_4 and R_5 each represent a C_1 alkyl (CH_3). The motivation would be based on the desire to make additional compounds as disclosed by the patent with the reasonable expectation that the compounds would be useful for treatment of diseases as disclosed by U.S. Patent No. 5,843,928.

6. Claims 1 and 2-17 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 3-15 of U.S. Patent No. 6,114,317. Although the conflicting claims are not identical, they are not patentably distinct from each other because they both recite compounds as defined by the patent wherein each of Y_1 and Y_2 represent hydrogen or a hydroxy-protecting group, Y_3, Y_4, Y_7 and Y_8 each represent a hydrogen atom, Y_5 and Y_6 together represents $=CR_4R_5$ wherein each of R_4 and R_5 represent hydrogen, Z is Y wherein x is 0, R_6/R_7 represent hydrogen/methyl, y is 3 and each of R_8, R_9 and R_{10} each represent a C_1 alkyl (CH_3). The motivation would be based on the desire to make additional compounds as disclosed by the patent with the reasonable expectation that the compounds would be useful for treatment of diseases as disclosed by U.S. Patent No. 6,114,317.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. Claims 1-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Deluca et al. (US Patent Nos. 5,843,928; 6,114,317 ; 6,392,071 and 6,696,431).

Each of Deluca et al. teach 2-alkylidene-19-nor-vitamin D compounds useful in treatment of metabolic bone diseases such as osteoporosis and osteomalacia, psoriasis and cancer such as colon cancer (see **'928**, col. 2, line 24 – col. 4, line 52, claims 1, 14-27, 30 and 33; **'317**, col. 4, line 66 –col. 6, line 44, col. 7, line 15 – col. 8, line 5; claims 1 and 3-15; **'071**, col. 2, line 34 – col. 3, line61, col. 4, line 57 – col. 5, line 41, col. 9, formulae II and IV; **'431**, col. 2, line 33 – col. 3, line 61, col. 4, line 51 – col. 5, line 33, cols. 8-9, formulae II and IV). The prior art also teaches the production of said 2-alkylidene-19-nor-vitamin D compounds utilizing the hydrindanones of formula II having the corresponding side chain (see **'928**, cols. 7-8, formulae II and IV; **'071**, col. 9, formulae II and IV; **'431**. cols. 8-9, formulae II and IV).

The instant claims differ from the above-cited references by reciting compounds not exemplified by the prior art. However, it would have been obvious to one having ordinary skill in the art at the time of the invention to select any of the species of the genus taught by the prior art, including that of the instant claims, because an ordinary

artisan would have the reasonable expectation that any of the species of the genus would have similar properties and, thus, the same use as the genus as a whole. For example, it would have been obvious to one having ordinary skill in the art at the time of the invention to make the compounds of formula I as disclosed by **'928** wherein R_6 and R_8 represent hydrogen, Z is Y wherein m is 0, R_1/R_2 is hydrogen/methyl, n is 3 and R_3, R_4 and R_5 each represent a C_1 alkyl (CH_3). The motivation would be based on the desire to make additional prior art compounds with the reasonable expectation that the compounds would be useful for treatment of diseases as taught by Deluca.

Telephone Inquiry

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Barbara P. Badio, Ph.D. whose telephone number is 571-272-0609. The examiner can normally be reached on M-F from 6:00am-3:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should

you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Barbara P. Badio, Ph.D.
Primary Examiner
Art Unit 1616

BB
June 18, 2004